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Re: REQUEST FOR PUBLIC PARTICIPATION IN A PROPOSITION 65 REGULATORY UPDATE PROJECT, October 19, 2007 [1]

Dear Dr. Denton and Ms. Monahan-Cummings:

The following is submitted on behalf of the Grocery Manufacturers Association in response to the above notice. We very much appreciate the opportunity to provide some suggestions on potential regulatory reforms to Proposition 65.

As Proposition 65 enters its third decade, it is certainly time to review how the statute and the regulations – most of which were adopted 20 years ago – have functioned to advance the intent of the voters. Given that there was no precedent for a statute like Proposition 65, it is to be expected that there have been a number of obstacles – some of them serious – to its serving its intended purpose. Whatever its benefits, there is no question that there are many respects in which it has imposed enormous costs and uncertainties on the business community and burdens on OEHHA and public enforcers with no commensurate public health benefit. The uncertainties and deficiencies have produced costly litigation that could be avoided with greater clarity in the regulations and with revisions that will better serve the statutory goals. The litigation has, in many instances, produced settlements prompted entirely by the defendants need to stem the costs of litigation – not by the legitimacy of the underlying claims; as a result, such settlements undermine the credibility of the statute and of

[1] http://www.oehha.ca.gov/prop65/public_meetings/notice101907.html

the warnings that the settlements call for. Worse, many important issues under the statute are now being resolved in litigation, based on arguments by two sides that each have a vested interest in a particular outcome, and without the benefit of OEHHA's expertise or of public input. In sum, we welcome OEHHA's decision to undertake meaningful regulatory reform.

We expect that the Agency will receive numerous proposals for reform, and our members themselves would probably support many of them. As this is the beginning of the process, we have limited ourselves to 7 areas of potential reform that are of particular importance to our members. We list them below. If the Agency concludes, as we hope it will, to pursue reforms in all or any of these areas, we would be very pleased, to provide you, with specific proposals and accompanying supporting materials upon your request.

1. Prioritization of Proposals. We urge OEHHA to prioritize the potential revisions to the regulations in order to address first those issues that would make a practical difference for the regulated and the enforcement community, i.e., focusing on issues that have created litigation, uncertainty, and accompanying cost. This would include addressing the issues listed below, as well as providing clarity about key terms which are presently so uncertain that compliance programs cannot be developed with any confidence. These terms include "the average consumer", "exposure", (including calculating hand-to mouth transfers, relevance of absorption as opposed to contact, determination of "micrograms per day"), when federal standards are preemptive, and many others that come up in the vast majority of Proposition 65 cases.

2. Use of the internet for warning programs. In the two decades since Prop 65 was passed, and since the so-called 800 number litigation, a lot has changed in the way people communicate, shop, and find information with respect to products they use and health issues of concern. We know that more people use computers than read newspapers and that health is one of, if not the single most researched subjects on the internet.[2] OEHHA should, therefore, consider changes in the real world, such as widespread use of cell phones, e-mail, and the Internet, and consider revisions to the regulations on how warnings are communicated and how notices are provided -- for example, allowing plaintiffs to send 60-day notices to public prosecutors by e-mail, incorporating internet warnings into regulatory schemes, particularly for consumer products. Advertisers have already learned that these electronic means are more efficient and effective ways of communicating than the old means of newspaper advertising or in-store signage.

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[2] Rutten L.F., Moser R.P., Beckjord E.B., Hesse B.W., Croyle R.T. (2007) Cancer Communication: Health Information National Trends Survey. Washington, D.C.: National Cancer Institute. NIH Pub. No. 07-6214 NIH, Health Information National Trends Survey; http://hints.cancer.gov/hints/docs/hints_report.pdf and **HINTS Briefs: Number 1** http://hints.cancer.gov/hints/docs/hints_briefs122705.pdf

3. For foods, a general in-store Proposition 65 warning statement directing consumers to a web site for product-specific information is most appropriate and more informative than the warning currently contemplated by the regulation. The current regulations provide that for many foods, the following warning shall be provided:

> "WARNING: Chemicals known to the State of California to cause cancer or birth defects or other reproductive harm may be present in foods or beverages sold or served here." [3]

The California Court of Appeal has also recognized that Proposition 65 chemicals may be present in thousands of foods in trace amounts and that those who sell those foods probably lack the knowledge or the resources to be able to make a no significant risk determination for foods that people have eaten safely for many years.[4].

A generic warning, supported by more specific nutritional information on a State web site would therefore not only be consistent with the existing regulations and case law, but would be a more effective means of providing information to consumers.

4. Section 12501 -- the "naturally occurring" chemical in food exception -- must be revised to make it meaningful and understandable to those developing compliance programs and enforcing the law. OEHHA's predecessor agency intended there to be a naturally occurring chemical exception for food products. As it exists, it is of value, if at all, only to businesses that have the resources and the will to litigate a case through trial. Most of the critical terms are ambiguous, thereby inviting litigation. The reference to Title 21 Code of Federal Regulations, Section 110.110, subdivision (c) of the FDA regulations is a mystery even to FDA experts as it seems to have no relevance to Proposition 65 issues. The *Nicolle-Wagner* court recognized the importance of having a working naturally occurring exception, and we urge OEHHA to make it so.

As a part of revising Section 12501, we recommend that the term "naturally occurring" be amended to include chemicals that are the by-product of cooking that are naturally occurring constituents in the foods.

5. Exclude retailers, acting solely as conduits to the consumer, from prosecution. Proposition 65 contemplated that there would be regulations limiting the liability of retailers to instances "where the retailer itself is responsible for introducing a [Proposition 65] chemical ...into the consumer product."[5] The absence of such regulation is unfair to retailers, does not serve public health goals and has allowed abuses of the statue where threatened and actual litigation against retailers is used as leverage to extract settlements from manufacturers. Twenty years later, we believe it is time for that regulation to be

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[3] Title 22 Calif. Code of Reg. §12601(b)(4)(C).
[4] ***Nicolle-Wagner* v. *Deukmejian* 230 Cal. App. 3d 652, at 660-662.**
[5] Cal. Health and Safety Code § 25249.11(f). http://www.oehha.ca.gov/prop65/law/P65law72003.html

adopted. By definition, it would advance the purposes – and the express language -- of the statute.

6. OEHHA should shift resources from listing to identifying safe harbors. Much of OEHHA's scientific resources in the Proposition 65 arena have, to this point, been devoted to listing chemicals. As a result, most of the chemicals that need to be listed have been listed and, absent a newly identified and significant carcinogen or reproductive toxin, we believe the statute would be better served by shifting those resources to developing Safe Harbor numbers in scientifically rigorous way.

7. Limit abuses of the statute by private prosecutors by giving the Attorney General a larger role in screening private claims and a more significant obligation on private prosecutors to show that they are efficiently serving a public, rather than private, interest. Regrettably, the private prosecutor provisions have in many instances been abused, imposing huge costs, undermining the statute and providing no public benefit. These provisions turn every nascent toxicology issue and every newspaper report of some new theory into a lawsuit, usually not involving any elected or appointed representative of the public. The uncertainty this breeds makes it very difficult for businesses -- what would be called the "regulated community" if Proposition 65 were implemented through clear and consistent regulations -- to know their obligations under the law so that they can meet them. As OEHHA itself recognizes, there is only so much that can be done to address this situation through administrative policies and regulatory revisions, as opposed to statutory revisions, but we believe the reforms identified above, as well as others more specifically directed to prosecutorial abuses by private entities, would make a difference.

As previously stated, we would be pleased to provide more detailed proposals on any of these recommendations should OEHHA decide to pursue them. We believe the Agency is engaged in an important exercise and we look forward to working with the OEHHA to improve the workings of the statute.

Sincerely,

Michèle B. Corash